APR 1 5 2003

EXHIBIT 1-B

EXHIBIT 21
510(K) SUMMARY

K030385

1. SUBMITTER

KAWASUMI LABORATORIES, INC.
3-28-15 MINAMI-OHI
SHINAGAWA-KU, TOKYO 140 JAPAN
PHONE:011-81-3-376-1151
FAX: 011- 81-3-376-3235
CONTACT: MR. KOJI SO

AGENT

KAWASUMI LABORATORIES AMERICA, INC.
4723 OAK FAIR BLVD.
TAMPA, FL 33610
PHONE: 813-630-5554
FAX: 813-630-5033
CONTACT: MR. JACK PAVLO

2. **NAME OF DEVICE**: KAWASUMI LABORATORIES IV ADD-ON FILTER ADMINISTRATION SET WITH AND WITHOUT Y CONNECT OR NEEDLELESS ACCESS CONNECTOR

   COMMON NAME: IV FILTER SET

3. **PREDICATE DEVICE**: K00142 - KAWASUMI LABORATORIES IV ADMINISTRATION SET

4. **DESCRIPTION OF THE DEVICE**: A STERILE, SINGLE USE ADD-ON FILTER ADMINISTRATION SET USED TO SERVE AS A CONDUIT FOR THE FILTRATION OF IV FLUID FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. THE DEVICE MAY INCLUDE A NEELELESS ACCESS CONECTOR WHICH ELIMINATES THE USE OF NEEDLES TO ACCESS THE SET DURING IV ADMINISTRATION AND AIDS IN THE PREVENTION OF NEELDESTICK INJURIES. THE FILTER PORE SIZE WILL BE .22 OR 1.2 MICRON WITH AN EFFECTIVE FILTRATION RATE (EFA) OF 10 CM^2.

6. **INTENDED USE**: THE IV ADD-ON FILTER ADMINISTRATION SET IS A STERILE, SINGLE USE DEVICE USED TO ATTACH TO A NON FILTERED IV ADMINISTRATION SET FOR THE PURPOSE OF FILTERING SOLUTION DURING INTRAVASCULAR ADMINISTRATION.

6.. **SIGNIFICANT PERFORMANCE CHARACTERISTICS**: THERE ARE NO SIGNIFICANT DIFFERENCES IN PERFORMANCE CHARACTERITICS BETWEEN THIS DEVICE AND THOSE OF THE SUBSTANTIALLY EQUIVALENT DEVICES MARKETED FOR SALE IN INTERSTATE COMMERCE. BOTH DEVICES FILTER OUT PARTICLES IN AN IV LINE ADMINISTERING A SOLUTION WHEN THOSE PARTICLES ARE LARGER THAN THE ..22 MICRON OR 1.2 MICRON PORE SIZE OF THE SPECIFIC FILTER CHOSEN.

7. **TECHNOLOGICAL CHARACTERISTICS**: THERE ARE NO DIFFERENCES BETWEEN THE TECHNOLOGICAL CHARACTERISTICS OF THIS DEVICE AND THOSE OF THE SUBSTANTIALLY EQUIVALENT DEVICE FROM KAWASUMI LABORATORIES BEING MARKETED FOR SALE IN INTERSTATE COMMERCE.

8. **PERFORMANCE DATA**: KAWASUMI LABORATORIES HAS CONDUCTED BIOCOMPATIBILITY TESTS ON THE BODY FLUID CONTACTING MATERIAL PORTIONS OF THE DEVICE AND KL BELIEVES THE BIOCOMPATIBILITY DATA SHOW THE DEVICE IS SUITABLE FOR ITS INTENDED USE.

9. **CONCLUSIONS**: THE DEVICE MEETS ALL BIOCOMPATIBILITY AND PYROGENICITY TEST REQUIREMENTS. THEREFORE, IT IS AS SAFE AS THE PREDICATE DEVICE AND PERFORMS AS WELL AS THE PREDICATE DEVICE.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 5 2003

Mr. Jack Pavlo
Technical Services Manager
Kawasumi Laboratories America, Incorporated
5905C Hampton Oaks Parkway
Tampa, Florida 33610

Re: K030385
Trade/Device Name: IV Add-on Filter Administration Set with and without Y Connect or Needleless Access Connector
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: February 4, 2003
Received: February 5, 2003

Dear Mr. Pavlo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K030385

EXHIBIT 23

INDICATIONS FOR USE

510(k) NUMBER (IF KNOWN): _____

DEVICE NAME: IV ADD-ON FILTER ADMINISTRATION SET WITH AND WITHOUT Y CONNECT OR NEEDLELESS ACCESS CONNECTOR

INDICATIONS FOR USE:

THE IV ADD-ON FILTER ADMINISTRATION SET USED TO ATTACH TO A NON FILTERED IV ADMINISTRATION SET FOR THE PURPOSE OF FILTERING SOLUTION DURING INTRAVASCULAR ADMINISTRATION. THE DEVICE MAY INCLUDE A NEELE FREE VALVE INJECTION SITE WHICH ELIMINATES THE USE OF NEEDLES TO ACCESS THE SET DURING IV ADMINISTRATION AND AIDS IN THE PREVENTION OF NEELDESTICK INJURIES.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Patricia Cusenza

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030385